Global Regulatory Policy

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October 25, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2004N-0408 Regulatory Site Visit Program

Merck & Co., Inc. is a leading worldwide, human health products company. Through a combination of the best science and state-of-the-art medicine, Merck's Research and Development (R&D) pipeline has produced many important pharmaceutical products available today. These products have saved the lives of or improved the quality of life for millions of people globally.

Merck is a leader in the development of vaccines that help protect against many serious diseases. Therefore, we are very interested and well qualified to respond to the opportunity afforded by the FDA Center for Biologics Evaluation and Research (CBER) Docket Number 2004N-0408, *Regulatory Site Visit Training Program*[1].

Merck has previously provided comment in support of Agency training programs. In our comments to the FDA Docket No. 2004N-0181 Critical Path Initiative (July 30, 2004) and the HHS Docket No. 2004S-0233 Solicitation of Comments on Stimulating Innovation in Medical Technologies (August 23, 2004) we stated: *The Agency (HHS) should fully support efforts to increase collaboration between the FDA, NIH, CDC, academia, and industry to focus on new technologies or emerging areas of science that may make the drug development process more efficient. For instance, the Agency could support the development of academic curricula for training students at various educational levels (undergraduate to graduate) that will provide, upon graduation, a cadre of applicants for the agencies, academic institutions, and the industry to choose from for entry level positions up to senior science advisors. In particular, FDA may also consider supporting a personnel exchange for agency staff to experience first hand what is involved in drug development from an industry perspective (from clinical decisions to analytical development) and for industry staff to experience the agency perspective. Allowing these personnel exchanges in a non-competitive, non-inspectional manner will foster a better understanding of the different perspectives, hopefully leading to a more streamlined drug development process.*

[1] 69 FR 57033, Docket No. 2004N-0408

Merck would like to invite CBER staff interested in vaccine development to visit with our vaccine R&D, regulatory affairs and manufacturing staff. We appreciate the opportunity to participate in the CBER Regulatory Site Visit Training Program. Please do not hesitate to contact me, should you have any questions.

If you would like to schedule the visit or outline an agenda, please contact my colleague, Taryn Rogalski-Salter PhD, Director Regulatory Affairs, at 484-344-4812 or taryn_rogalskisalter@merck.com.

Sincerely,

Lauren M. Hetrick

for Keith Chirgwin, MD
Executive Director
Worldwide Vaccines Regulatory Affairs